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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,270	09/29/2003	Christopher S. de Voir	117163.00092	3098

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EXAMINER	
BROWN JR, NATHAN H	
ART UNIT	**PAPER NUMBER**
2121	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/674,270	DE VOIR ET AL.	
	Examiner	Art Unit	
	Nathan H. Brown, Jr.	2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *(3)* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Examiner's Detailed Office Action

1. This Office Action is responsive to the communication for application 10/674,270, filed April 26, 2007.

2. Claims 1-6 and 8-17 are pending. Claims 1-6 and 8-17 were previously presented.

3. After the previous office action, claims 1-6 and 8-17 stood rejected.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller et al.* (USPN 6,594,524) in view of *Voelz* (USPN 4,779,100).

Regarding claim 1. *Esteller et al.* teach an apparatus for the classification of physiological events (*see* Abstract, *Examiner interprets "forecasting" to be a classification task where the*

input is a description of some earlier event and the output is the identification of some event that follows (or results from) the earlier event.), comprising:

a signal input for the input of a physiological signal representing or constituting a physiological event (*see* col. 9, lines 34-36); and

a classification unit (*see* Fig. 3, item 200 "Intelligent Data Processing Unit") for classifying the physiological signal on the basis of its signal shape (*see* col. 18, lines 44-50), the classification unit comprising:

a transformation unit which is designed to carry out transformation of the physiological signal in such a way that as the output signal it outputs a number of values representing the physiological signal and based on the transformation (*see* Fig. 4, preprocessing 210 and feature extraction; col. 9, lines 20-25; col. 20, lines 26-36); and

a probabilistic neural network which is connected to the transformation unit to receive the values (see Fig. 32, col. 36, lines 43-50) and which contains a number of event classes which represent physiological events (see Fig. 32, col. 36, lines 30-33) and which in turn are each represented by a set of comparative values, which probabilistic neural network is adapted on the basis of the comparison of the values with the comparative values to effect an association of the physiological signal represented by the values with one of the event classes (*see* col. 36, lines 55-56 and col. 37, lines 27-36, *Examiner interprets "weights used at the hidden layer of the PNN" to be comparative values, which the probabilistic neural network is adapted on.*).

Esteller et al. do not teach an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to

the transformation unit, the adjusting unit connected upstream of the transformation unit. However, *Voelz* does teach an adjusting unit for centering the physiological signal in a time window of predetermined window width and for outputting the centered physiological signal to the transformation unit (*see* Fig. 2 and Abstract, *Examiner interprets "the sensitivity or balance control of each polygraph electronic module" (see* Fig. *2) to be an adjusting unit. Examiner interprets the "circuitry having a monostable multivibrator configured as a non-retriggerable one shot device responsive to the voltage change signal from the detector to provide a single pulse driving signal to a pen driving motor" to be the transformation unit.*), the adjusting unit connected upstream of the transformation unit (*see* Abstract, Examiner interprets the "sensitivity or balance potentiometer" and "detector in the form of a differentiator for detecting a change in voltage on the wiper of the sensitivity or balance potentiometer that produces a signal indicative of the voltage change" to be connected upstream of the transformation unit.).

It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine *Esteller et al.* with *Voelz* to obtain an apparatus capable of indicating a change in the control setting of an instrument.

Regarding claim 2. *Esteller et al.* teaches the apparatus of claim 1, wherein: the transformation unit is adapted for executing .the transformation operation on the basis of wavelets and a transformation rule determining the values to be outputted using the wavelets (*see* col. 28, lines 21-44).

Regarding claim 3. *Esteller et al.* teaches the apparatus of claim 2, wherein: the comparative values of the probabilistic neural network are based on a transformation procedure in which the same wavelets and the same transformation rule as in the transformation unit are used (*see* Fig. 32, col. 37, lines 10-17; inputs of the neural network come from the outputs of transformation unit, therefore said comparative values are based on the transformation procedure).

6. Claims 4-6, 8, 9, and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller et al.* in view of *Voelz* and further in view of *Echauz et al.* (USPN 6,678,548).

Regarding claims 4, 11, and 12. *Esteller et al.* teaches the apparatus of claim 3, wherein the probabilistic neural network further comprises: at least one ascertaining unit for determining association probabilities of the physiological signal with the event classes on the basis of the comparison of the values with the comparative values of the respective event class and for outputting the ascertained association probabilities (*see* Fig. 32, col. 37, lines 11-20). *Esteller et al.* does not expressly teach selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to associate the physiological signal with the event class having the highest association probability (it is disclosed in Fig. 32 as competitive layer, but without. a detailed explanation). However, *Echauz et al.* teaches selection unit which is connected to the ascertaining unit for receiving the association probabilities and which is adapted to extract the highest association probability from the association probabilities and to

associate the physiological signal with the event class having the highest association probability (*see* col. 26, lines 36-39 mention competitive layer as a maximum selector; *see* also col. 18, lines 53-66). It would have been obvious to a person of ordinary skill in the art at the time of the invention to include the details on implementation of a probabilistic neural network from *Echauz et al.* and combine it with the probabilistic neural network of *Esteller et al.* in order to find the details of how the probability of having a seizure is estimated.

Regarding claim 5. *Esteller et al.* teaches the apparatus of claim 4, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (*see* col. 13, lines 39-44).

Regarding claim 6. *Esteller et al.* teaches the apparatus of. claim 5, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (*see* Fig. 32, T values; col. 37, lines 22-26), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities and , upon extraction of the highest association probability uses the average values instead of the individual values (*see* Fig. 32, averaging operation on Ts is shown in circles in the output layer; col. 37, lines 12-20, averaged T1 and T2 form probabilities PI and P2 correspondingly).

Regarding claim 8. *Esteller et al.* do teach the apparatus of claim 6. *Esteller et al.* do not teach the apparatus of claim 6, wherein: in those event classes which include two or more sets of comparative values representing the same event class, the sets of comparative values correspond to different offsets in the centering of the centered physiological signal. *Voelz* does teach that, in those event classes which include two or more sets of comparative values representing the same event class (*see* Fig. 1 and col. 2, line 66 to col. 3, line 14), the sets of comparative values correspond to different offsets in the centering of the centered physiological signal (*see* col. 3, lines 15-20, *Examiner interprets adjustments of "the balance or centering on chart **10**" to correspond to different offsets in the centering of the centered physiological signal.*). It would have been obvious at the time the invention was made to persons having ordinary skill in the art to combine *Esteller et al.* with *Voelz* to obtain an apparatus capable of indicating a change in the control setting of an instrument.

Regarding claim 9. *Esteller et al.* teaches an implantable medical device characterized in that it is provided with an apparatus for the classification of physiological events as set forth in claim 8 (*see* Abstract).

Regarding claim 13. *Esteller* teaches the apparatus of claim 1, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (col. 13, lines 39-44).

Regarding claim 14. *Esteller et al.* teaches the apparatus of claim 11, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (*see* col. 13, lines 32-36, *Examiner interprets "electrical, magnetic, chemical, sensorial or cognitive stimulation variables" to be comparative values representing the same event class are present for at least one event class.*).

Regarding claim 15. *Esteller et al.* teaches the apparatus of claim 12, wherein: two or more sets of comparative values representing the same event class are present for at least one event class (*see* above).

Regarding claim 16. *Esteller et al.* teaches the apparatus of claim 14, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (*see* Fig. 32, col. 37, lines 21-26, *Examiner interprets the entries of Matrix T to determine a plurality of association probabilities for each event class.*), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average values of the corresponding association probabilities (*see* Fig. 32, *Examiner interprets the output units P_1 and P_2 to form the average of T_{1j} and T_{2j}, respectively, where each T_{ij} is "the probability that the input signals belong to the pre-seizure/seizure class"*.) and upon extraction of the highest association probability uses the average values instead of the individual values (*see* Fig. 32, *Examiner interprets the units of the "Competitive Layer" to extract the*

highest association probability by picking one of P_1 or P_2 which use the average of T_{1j} and T_{2j}, respectively.).

Regarding claim 17. *Esteller et al.* teaches the apparatus of claim 15, wherein: the ascertaining unit is adapted to determine a plurality of association probabilities for each event class which has two or more sets of comparative values representing the same event class (*see* Fig. 32, col. 37, lines 22-26, *Examiner interprets the entries of Matrix T to comprise two or more sets of comparative values representing the same event class (e.g., T11 and T21 emanate from the same hidden unit, which represents a class of pre-seizure data).*), and the selection unit is so designed that, for those event classes which have two or more sets of comparative values representing the same event class, it forms average, values of the corresponding association probabilities and upon extraction of the highest association probability uses the average values instead of the individual values (*see* Fig. 32, *Examiner interprets the units of the "Competitive Layer" to extract the highest association probability by picking one of P_1 or P_2 which use the average of T_{1j} and T_{2j}, respectively.*).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Esteller et al.* (US Patent No. 6,594,524) in view of *Echauz et al.* (US Patent No. 6,678,548), and further in view of *Igel et al.* (US Patent No. 6,192,273).

Regarding claim 10. *Esteller et al.* teach the implantable medical device of claim 9 (*see* Abstract). *Esteller et al.* and *Echauz et al.* do not teach that the implantable medical device is in

the form of a cardiac pacemaker or defibrillator. *Igel et al.* teach that the implantable medical device is in the form of a cardiac pacemaker or defibrillator (*see* Fig. 1, col. 3, lines 24-34, *Examiner interprets "device 10 may optionally comprise a therapy system 70 for delivering electrical shock or pacing impulses" to mean an implantable medical device is in the form of a cardiac pacemaker or defibrillator.*). It would have been obvious to a person of ordinary skill in the art, at the time of the invention, to combine the probabilistic neural network classifier from *Esteller et al.* and *Echauz et al.* with the implantable device of *Igel et al.* to obtain a neural network classifier for "adaptively sampling a cardiac electrical signal for use in a heart rhythm classifier" (*see Igel et al.*, col. 2, lines 38-40).

Response to Arguments

Rejection of Claims 1 and 8 under 35 U.S.C. 103(a)

8. Applicants' arguments filed April 26, 2007 with respect to the rejection of claims 1 and 8 under 35 U.S.C. 103(a) as being unpatentable over Esteller et al. (USPN 6,594,524) in view of Hively et al. (USPN 6,484,132) have been fully considered but are not moot under new grounds of rejection.

Rejection of Claims 4, 11, and 12 under 35 U.S.C. 103(a)

9. Applicnats argue that

> As described above and as admitted by the Examiner, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Furthermore, Echauz et al. (US Patent No. 6,678,548), hereinafter Echauz, does not teach or suggest a centering of a physiological signal in a time window as does the

> claimed invention of claim 1. Therefore, in view of at least the foregoing and the fact that claims 4, 11, and 12 depend either directly or indirectly from independent claim 1, it is respectfully submitted that claims 4, 11, and 12 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 4, 11, and 12 under 35 U.S.C. 103(a) be removed.

Examiner responds that claim 1 is rejected on new grounds, thus claims 4, 11, and 12, which depend either directly or indirectly from independent claim 1, are also rejected under 35 U.S.C. 103(a).

Rejection of Claim 10 under 35 U.S.C. 103(a)

10. Applicnats argue that

> As described above and as admitted by the Examiner, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Furthermore, neither Echauz nor Iget et al. (US Patent No. 6,192,273), hereinafter Igel, teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Therefore, in view of at least the foregoing and the fact that claim 10 depends indirectly from independent claim 1, it is respectfully submitted that claim 10 defines allowable subject matter as well. Applicants respectfully request that the rejection of claim 10 under 35 U,S.C, 103(a) be removed.

Examiner responds that claim 1 is rejected on new grounds, thus claim 10, which depends either directly or indirectly from independent claim 1, is also rejected under 35 U.S.C. 103(a).

Rejection of Claims 2, 3, 5, 6, 9, and 14-17 under 35 U.S.C. 103(a)

11. Applicnats argue that

> As described above and as admitted by the Examiner, Esteller does not teach or suggest a centering of a physiological signal in a time window as does the claimed invention of claim 1. Therefore, in view of at least the foregoing and the fact that claims 2, 3, 5, 6, 9, and 14-17 depend either directly or indirectly from independent claim 1, it is respectfully submitted that claims 2, 3, 5, 6, 9, and 14-17 define allowable subject matter as well. Applicants respectfully request that the rejection of claims 2, 3, 5, 6, 9, and 14-17 under

35 U.S.C. 103(a) be removed.

Examiner responds that claim 1 is rejected on new grounds, thus claims 2, 3, 5, 6, 9, and 14-17, which depend either directly or indirectly from independent claim 1, is also rejected under 35 U.S.C. 103(a).

Correspondence Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan H. Brown, Jr. whose telephone number is 571-272- 8632. The examiner can normally be reached on M-F 0830-1700. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Knight can be reached on 571-272-3687. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anthony Knight
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Nathan H. Brown, Jr.
June 24, 2007